

**Notice of Allowability**

Application No.

09/976,219

Examiner

Samuel W Liu

Applicant(s)

OR ET AL.

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 3-30-04, 10-15-03, 11-3-03 and 11-21-03.
2. ☒ The allowed claim(s) is/are 12-17 and 19-21.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                                |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>4-7-04</u> . |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date <u>2-21-03</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment  |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                              | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance                       |
|   | 9. <input type="checkbox"/> Other _____.   |

### **DETAILED ACTION**

This Office action is in response to applicant's amendment filed 30 March 2004, which cancels claims 1-11, and amends claims 12 and 14-16. Note that claim 18 is cancelled by applicants' amendment filed 21 November 2003. The above indicated amendment has been entered. Note that the references listed in IDS filed 21 February 2003 have been considered. Yet, note that the IDS filed 21 August 2003 is a duplicated copy of the IDS filed 10 September 2003 which was considered.

Also, note that the terminal disclaimer filed on 15 October 2003 and the terminal disclaimer filed 3 November 2003, disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of US Application Nos. 09/800856 and Application No. 09/975923, respectively, have been reviewed and are accepted.

The pending claims 12-17 and 19-21 are therefore examined in this Office action.

### **EXAMINER'S AMENDMENT**

An Examiner's Amendment to the record appears below. Should the change and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Jason D. Ferrone on April 7, 2004. Applicant agrees the examiner proposed amendment to claims 12, 14-16 and 19-21 (see below).

#### **Amendments to the claims:**

The pending claims 12, 14-16 and 19-21 have been amended as follows. Please replace the previous claims with the claim shown below.

Claim 12 (*Twice amended*): before "as claimed in claim 15" change "formula I" to "formula (I)".

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Claim 14 (*Twice amended*): before “as claimed in claim 15” change “formula I” to “formula (I)”.

Claim 15 (*Twice amended*): before “a pro-drug” change “formula I” to “formula (I)”.

Claim 16 (*Twice amended*): After “claim 15 defined by” change “formula I” to “formula (I)”.

Claim 19 (*Amended*): before “as claimed in claim 15” change “formula I” to “formula (I)”.

Claim 20 (*Amended*): After “heteroaryl” add “group”.

Claim 21 (*Amended*): After “(2'-methyl)furan-2-yl” add “group”.

The following is an **Examiner's Statement of Reasons for Allowance**:

The prior art of record does not teach or suggest the disclosed cyclosporin compound and method of treating autoimmune disease and preventing organ transplantation is subject comprising administering said cyclosporin compound. Claims 12-14 are drawn into a method of treating autoimmune disease and a method of preventing organ transplantation. Claims 15-17 and 19-21 are drawn to the allowable product, i.e., the above-mentioned cyclosporin compound. In consideration of the method claims 12-14, pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), are subject to being rejoined. Process claims 12-14, previously drawn to non-elected invention, are hereby rejoined and fully examined for patentability under 37 CFR 1.104. The claims 12, 14-16 and 19-21 are therefore allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is (571) 272-0949. The Examiner can normally be reached daily except alternate Fridays from 8:30 A.M. to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached at (571) 272-0951. The official fax number for Technology Center 1600 is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

SWL

Samuel W. Liu, Ph.D.

April 7, 2004

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER